



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,605	01/20/2004	Jan Weber	12013/51401	8100
23838	7590	01/02/2008		
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 01/02/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/759,605

Applicant(s)

WEBER ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 6, 8, 12, 14-20, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9, 10, 13, 21, 22, 25-33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/24/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/07 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5,9,13,25-27,30 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt et al. (6217607). Fig. 3 shows a stent substrate **15** having a catalyst coated **50** thereon and a filter layer **80** on the outer area. Alt discloses the filter layer prevents thrombus formation (col. 7, lines 46-51) and inflammation (col. 10, lines 46-48), which results from red and white blood cells. Thus, the filter retards passage of white and red blood cells since it stops thrombi from forming. Fig. 1 shows a stent body with struts. Alt discloses the stent is made of a non-polymer and covered with a catalyst metal and is capable of being pretreated to increase its surface area since Alt discloses

it is designed to cover the whole surface and have an excellent bond to the stent surface, col. 7, lines 7,8,11,12,20-24. Alt discloses the outer filter is mesoporous or a ceramic-like material, col. 8, lines 6-10.

Claims 1-5,7,9,10,13,25,30 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson (5690670). Davidson discloses a medical implant with a body having a first surface covered with a catalyst such as titanium oxide, col. 7, lines 8-11. Davidson also discloses the stents can include a therapeutic agent, col. 14, lines 60-64 and col. 16, lines 48-52. Davidson also discloses that coatings applied to medical implants can be polymers and ceramics can be applied on the surface of the implant that are hemocompatible or resist thrombus formation and act as a covering, col. 11, lines 59-66 and col. 12, lines 49-67. Davidson also discloses the use of a porous coating on the stent, col. 4, lines 56-66.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21,22,28,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. '607 in view of Smalley et al. (2002/85968). Alt et al. is explained supra. Alt does disclose the filter material can be iridium oxide, col. 7, lines 46-48. However, Alt et al. fail to disclose alternative filter material or coverings for the composite stent. Smalley et al. teach the use of catalysts with carbon nanotubes or bucky paper coated onto to composites including implants and prostheses, paragraphs 121,276. Smalley

also teaches that the bucky paper is useful in supporting catalysts on devices (paragraph 126) and to provide a composite device resisting delamination, paragraph 14. Smalley additionally teaches the bucky paper can be used with oxides, paragraphs 94,166,268. Smalley also teaches that polymers can be applied to enclose the composite material and provide the bulk or support for the body framework, paragraphs 257,259. It would have been obvious to one of ordinary skill in the art to incorporate bucky paper and a polymer matrix as taught by Smalley et al. with the stent of Alt et al. such that it improves the adherence of the layers formed on the stent material and provide a supportive device that will not collapse or degrade.

Claims 31-33,35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kula et al. '825 in view of Alt et al. '607. Kula et al. show (Figs. 1a-d,2,3a,b,4,6-9) different strut patterns for stents. Figs. 11,12 show that the stent has a tapered cross-section. It is inherent that a strut will have a smaller area for the areas toward the outside of the stent in locations where the stent has a smaller or tapered thickness. Kula also discloses the stent is expandable, col. 4, lines 15-18. However, Kula fails to disclose the use of a catalyst and filter. Alt is explained supra. Alt discloses the outer coating layer or oxide aids in reducing inflammation, col. 10, lines 41-47. It would have been obvious to one of ordinary skill in the art to incorporate the catalyst and filter material on the stent as taught by Alt et al. such that the stent of Kula et al. can provide a limited inflammatory response when implanted.

Response to Arguments

Applicant's arguments filed 9/24/07 have been fully considered but they are not persuasive. Applicant alleges that Alt's outer filter layer does not retard white and red blood cells. However, Alt clearly discloses that the outer layer prevents the immune responses associated with these cells and thus "retards" the passage of these cells.

In response to applicant's argument that there is no suggestion to combine Alt with the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Alt provides an biological effective stent for insertion in the blood vessel and to substitute materials or design is well within the skill of a surgeon and engineer developing a therapeutic device for patients. These are highly skilled individuals.

Applicant additionally argues that Davidson also does not disclose a retarding filter for red and white blood cells. However, the Examiner would like to indicate that it is well known that sheath, coverings etc. on implants that are lubricious are inherently non-porous to white and red blood cells so that no clots form as the stent is implanted in the patient. Additionally Davidson states the coating would be compatible, such that it inherently would not permit thrombi from forming. If thrombi occur then restenosis will require the patient to have secondary procedures. Any person of ordinary skill in the art

Art Unit: 3738

would understand that coatings on stents would not be developed to promote thrombus (permitting white and blood cell passage) for the risk of a serious medical condition to the patient. Thus, Applicant's comments about Davidson's coating are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

